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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,772	07/02/2001	Philip Needleman	01-481-D	2863

7590

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EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 08/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/898,772

Applicant(s)

NEEDLEMAN, PHILIP

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

### **DETAILED ACTION**

This application is a continuation application of serial No. 09/402,076. The newly executed declaration submitted September 17, 2001 does not identify the parent application. A copy of the declaration from the parent application is required in this application to properly claim the foreign priority. Note this application filed on July 2, 2001, more than 30 months after the PCT filing date, March 30, 1998.

#### ***Claim Rejections 35 U.S.C. 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 9-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Particularly, applicants provide no description or any working example with respect to how the method would prevent a dementia in general, or Alzheimer's disease in particular. It is known in the art that the dementia herein are mostly closely related to aging, the precise etiology is not known, and there is no known pharmaceutical agents would prevent such age-related disorder. See, Merck manual page 1336-1340. Further, it is known in the art that COX-II inhibitor are known only for treating Alzheimer's disease in slowing the progression of the disorder. No evidence show COX-II inhibitor would prevent Alzheimer's disease. See, page 366, the right column and page 369, the left column in Sramek et al. Also, the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed of physiological activity.

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Therefore, in view of the nature of the claimed invention, the relative skill of those in the art, the predictability of the art, and the absence of working example in the specification, the claimed invention is not enabled.

***Claim Rejections 35 U.S.C. 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ducharme et al. (WO 96/11676, IDS) in view of Talley et al. (US Patent 5,760,068).

5. Ducharme et al. teach a method for treatment of neurodegenerative disease Alzheimer disease by administering selective COX-II inhibitors to patient in need. COX -II inhibitors in general are known to have anti-neurodegenerative effect, and are useful for treating neurodegenerative disease. Ducharme et al. further teach that benzenesulfonamide derivatives are known to be useful as selective COX-II inhibitors. See particularly, page 2.

6. Ducharme et al. do not teach expressly the employment of pyrazol-1-yl benzenesulfonamide compounds herein as the COX-II inhibitors.

7. However, Talley teaches that the compounds employed herein are known selective COX-II inhibitors. See, particularly, column 4, lines 57-67 and the claims.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the compounds herein as COX-II inhibitors in Ducharme's method.

A person of ordinary skill in the art would have been motivated to employ the compounds herein as COX-II inhibitors in Ducharme's method because the compounds herein are known to have high selectivity of inhibiting COX-II (not COX-I), which is preferred in Ducharme's method.

8. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Isakson et al. (US Patent 6,136,839, IDS)

9. Isakson et al. teach that the benzenesulfonamide compounds, including compounds employed herein, are known COX-II inhibitors and suggest that the compounds would be useful for treatment of certain central nervous system disorder including Alzheimer's disease. See, particularly, column 3, lines 14-65, column 4, lines 25-30, column 7, lines 56-57, column 10, lines 62-67.

10. Isakson et al. do not teach expressly the employment of the compounds claimed herein for treating Alzheimer's disease.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ the COX-II inhibitors herein for treatment of neurodegenerative disease such as Alzheimer's disease since the prior art have already suggested that the compounds herein is beneficial for Alzheimer's disease. The selection

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of the particular compounds herein is seen to be a selection from amongst equally suitable material absent evidence to the contrary. Ex parte Winters 11 USPQ 2<sup>nd</sup> 1387 (at 1388).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Russell Travers, J.D., can be reached on (703) 308-4603. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner



Shengjun Wang

August 14, 2002